



STATE OF INDIANA

OFFICE OF THE ATTORNEY GENERAL

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OFFICIAL OPINION 2022-1

The Honorable Mike Gaskill
Indiana Senate
200 W. Washington Street
Indianapolis, Indiana 46204

The Honorable Eric Koch
Indiana Senate
200 W. Washington Street
Indianapolis, Indiana 46204

The Honorable James Tomes
Indiana Senate
200 W. Washington Street
Indianapolis, Indiana 46204

The Honorable Jim Lucas
Indiana House of Representatives
200 W. Washington Street
Indianapolis, Indiana 46204

The Honorable Elizabeth Rowray
Indiana House of Representatives
200 W. Washington Street
Indianapolis, Indiana 46204

RE: Off-label prescription of medications for treatment and prevention of COVID-19

Dear Senators Gaskill, Koch, and Tomes, and Representatives Lucas and Rowray:

The Indiana Office of the Attorney General (“OAG”) received separate requests, one from each of you, regarding health care providers (“HCPs”) prescribing certain medications “off-label” for the treatment or prevention of COVID-19. You expressed concern that your constituents were receiving consumer complaints for prescribing medications off-label for the treatment of COVID-19, and fear that third-party complaints may create barriers and interfere with the provider-patient relationship. If a provider risks a complaint or action against his or her professional license when prescribing medications off-label, it may affect their decisions regarding patient care. Although the requests were submitted independently, the language varies only slightly, while the intent is clearly the same – to ask this office to opine on the legality of off-label prescription for medications for the treatment and prevention of COVID-19.

QUESTION

Your requests all centered around physicians and other health care providers who have prescription authorization to prescribe medication, such as ivermectin or hydroxychloroquine, that is FDA-approved for another use, to treat or prevent COVID-19 in a patient. The question restated

thusly is whether these individuals may prescribe a medicine off-label for the treatment or prevention of COVID-19?

BRIEF ANSWER

Physicians and other HCPs with prescription authority licensed in Indiana may prescribe medication off-label for the treatment and prevention of COVID-19, as well as other illnesses and conditions. Off-label prescribing and use of medications is a common and widespread practice in health care and falls within the standard of competent care unless additional circumstances would otherwise qualify it as malpractice. However, the provider should consider informing the patient that the use is not an FDA-approved use to reduce the provider’s potential legal liability should a negative medical reaction occur.

ANALYSIS

Relevant Laws and Rules

Federal Food, Drug, and Cosmetic Act

The U.S. Food and Drug Administration (“FDA”) is the federal regulatory agency responsible for approving most human and animal food, all human drugs, biologics, animal products, and animal drugs; it also regulates cosmetics and other consumer products that emit radiation.¹ The Food, Drug, and Cosmetic Act (“FDCA”) was enacted in 1938 and authorizes the FDA to regulate drug and medical devices for safety and effectiveness, and issue food standards.² It is important to note that the FDCA gives the FDA authority to regulate drugs but not the practice of medicine. Explicit provisions in subsequent FDCA amendments, the FDA Modernization Act of 1997 and the FDA Amendments Act of 2007, prohibit the FDA from “limit[ing] the practice of medicine.”³

Indiana Law and Administrative Code

Title 25 of the Indiana Code regulates professions and occupations for the state. Ind. Code art. 25-1 contains general provisions, and includes the establishment of the Indiana Professional Licensing Agency (“IPLA”). *See* Ind. Code ch. 25-1-5. The IPLA performs certain administrative functions for several professional boards. *See* Ind. Code §§ 25-0.5-5-5, -7. The OAG receives, investigates, and, when appropriate, prosecutes complaints relating to licensed professionals.⁴ Ind. Code ch. 25-1-7.

¹ <https://www.fda.gov/regulatory-information/laws-enforced-fda> (last accessed October 27, 2021)

² *Id.*

³ George Horvath, *Off-Label Drug Risks: Toward a New FDA Regulatory Approach*, 29 *Annals Health L. & Life Sci.* 101, 116 (2020); *see also* Wendy Teo, *FDA and the Practice of Medicine: Looking at Off-Label Drugs*, 41 *Seton Hall Legis. J.* 305, 307-8 (2017).

⁴ The complaint and investigation process will be discussed in more detail in the *Standard of Care for HCPs* section, *infra*.

Ind. Code ch. 25-1-9 establishes minimum standards of practice for health professions, including physicians, advanced practice nurses, and physician assistants.⁵ Ind. Code § 25-1-9-4 establishes the standards of professional practice for these HCPs, but these activities do not solely include the provision of direct care to a patient.

Ind. Code art. 25-22.5 specifically regulates the practice of medicine and osteopathic medicine. Ind. Code ch. 25-22.5-2 creates the Medical Licensing Board of Indiana (MLB”), which enforces Ind. Code art. 25-22.5 and establishes licensing and examination standards for physicians. It also sets the standards of competent medical practice. *Id.* Title 844 of the Indiana Administrative Code contains the rules of the MLB. 844 IAC 5 provides additional standards of professional conduct and also the competent practice of medicine, i.e., the standard of care for physicians.

Ind. Code art. 25-23 regulates the nursing profession, and Ind. Code §§ 25-23-1-19.4, -19.5, -19.6, and -19.7 specifically discuss advanced practice nurses (“APNs”). Ind. Code § 25-23-1-19.4 requires an APN to operate in conjunction with a licensed practitioner and Ind. Code § 25-23-1-19.5 grants prescriptive authority to an APN who satisfies certain requirements. Ind. Code § 25-23-1-2 creates the Indiana State Board of Nursing, which regulates the nursing profession. The Board establishes standards for licensure and nursing education as well as examination requirements. *Id.* 848 IAC 2 establishes the standards for the competent practice of registered nursing. 848 IAC 4 establishes standards for the competent practice of APNs. 848 IAC 5 provides rules regarding prescriptive authority for APNs, including guidelines on prescribing opioids.

Ind. Code art. 25-27.5 regulates the physician assistant (“PA”) profession, and Ind. Code ch. 25-27.5-3 creates the Physician Assistant Committee. The Committee approves or rejects license applications and renewals, and recommends to the MLB rules for fees and standards of competent practice of PAs. Ind. Code §§ 25-27.5-3-5, -6. Ind. Code ch. 25-27.5-5 sets forth the scope of practice of a PA and makes clear the PA may not practice independently of a collaborating licensed physician. Ind. Code § 25-27.5-5-2(a); *see also* Ind. Code § 25-27.5-5-3 and Ind. Code ch. 25-27.5-6. Ind. Code § 25-27.5-5-4 grants PAs prescriptive authority as delegated by the collaborating physician but may not prescribe or dispense a schedule I controlled substance. *See also* Ind. Code § 25-27.5-5-6. 844 IAC 2.2 provides general administrative regulation of PAs, and 844 IAC 2-2-6 establishes the standards of competent practice of PAs.

Ind. Code ch. 25-1-20, known as the COVID Shield Law, provides immunity from liability for certain HCPs for certain health care services provided in response to COVID-19 after February 29, 2020, and before April 1, 2022 (if the state of disaster emergency is still declared at that time). *See* Ind. Code §§ 25-1-20-1, -2. Prescribing a medication off-label does “not constitute gross negligence, willful or wanton misconduct, fraud, or intentional misrepresentation under this chapter if performed in response to or arising from a state disaster emergency declared under IC 10-14-3-12 to respond to COVID-19.” *See* Ind. Code § 25-1-20-4(b)(3).

⁵ We limit our discussion to these three professions because they are the three HCPs with prescriptive authority for human patients in the state of Indiana.

“Off-Label” Use of Medications

In its simplest terms, “off-label” use means any use of a drug that is not FDA-approved.⁶ **This is a bit of a misnomer, however, because “[t]he FDA does not “approve” uses at all, and only approves products in the context of labeling for their intended uses.”**⁷ Therefore, a more technically correct description is any use by a HCP that deviates from the use or patient conditions *described on the label* (i.e., approved by the FDA) is an off-label use.⁸ Off-label use is not prohibited by the FDA or the FDCA, and as previously noted, FDCA amendments explicitly prohibit the FDA from regulating physicians and the practice of medicine. Per the FDA, once a drug is FDA-approved, HCPs may prescribe it “for an unapproved use when they judge that it is medically appropriate for their patient.”⁹

Off-label prescribing is a common medical practice. *Sidney Hillman Health Ctr. of Rochester v. Abbott Labs., Inc.*, 782 F.3d 922, 927 (7th Cir. 2015). Although it varies depending on the field, off-label prescription use is most common in oncology, rare diseases, AIDS treatment, and pediatrics, while the medication types most often prescribed off-label are anticonvulsants, antipsychotics, and antibiotics.¹⁰ Off-label use accounts for 21-60% of all prescriptions, and in some medical fields, the number is higher.¹¹ In certain cases, off-label use of a medication has become *the* standard of care for the treatment of a condition or illness because that medication represents the best – or only – treatment option available.¹² Examples of off-label uses of medications include: paroxetine in children (FDA-approved antidepressant for adults)¹³; metformin to treat polycystic ovarian syndrome (FDA-approved to treat diabetes)¹⁴; and ketamine to treat depression and migraines (FDA-approved anesthetic).¹⁵

While off-label prescribing is common, this does not mean it is always safe. More well-known examples of widespread off-label use of medications that caused significant harm are fenfluramine (commonly known as fen-phen)¹⁶ and oxycontin.¹⁷ Fenfluramine was used for long-term weight loss, although it was never intended to be prescribed as a long-term medication; it

⁶ <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label> (last accessed Oct. 28, 2021).

⁷ James M. Beck, *Off-Label Use in the Twenty-First Century: Most Myths and Misconceptions Mitigated*, 54 UIC J. Marshall L. Rev. 1, 7 (2021); *see also* Teo, *supra* note 3, at 311.

⁸ *Id.*

⁹ <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label> (last accessed Oct. 22, 2021)

¹⁰ Teo, *supra* note 3, at 311-12.

¹¹ Margaret Z. Johns, *Informed Consent: Requiring Doctors to Disclose Off-Label Prescriptions and Conflicts of Interest*, 58 Hasting L.J. 967, 968, 976-77 (2007); Horvath, *supra* note 3, at 102; Beck, *supra* note 7, at 25-6.

¹² Johns, *supra* note 11, at 976-77; Beck, *supra* note 7, at 30.

¹³ Teo, *supra* note 3, at 311.

¹⁴ *Id.*

¹⁵ Congressional Research Service, *Off-Label Use of Prescription Drugs*, Feb. 23, 2021, p. 5 (Table 1).

¹⁶ *Id.* at 6; Johns, *supra* note 11, at 977.

¹⁷ Johns, *supra* note 11, at 977.

caused heart valve damage to hundreds of thousands of patients.¹⁸ Oxycontin was intended to be used for patients with severe pain, as it is highly addictive (since it is an opioid), yet instead it was also widely prescribed for general pain relief; this has led to numerous addictions, injuries, and deaths that would otherwise not have occurred.¹⁹

HCPs should be cognizant of the risks as well as the benefits of off-label use of prescription medications, and ensure he or she is making an informed decision prior to prescribing the medication to determine the optimal treatment for the patient. It is also important the HCP communicate these with the patient. Informing the patient that the drug is not FDA-approved may reduce the HCP's liability should some sort of harm occur.²⁰ This, however, is no different than any other aspect of the HCP's provision of health care services and treatment of the patient. Off-label prescribing is a standard and common practice in medicine. Even the federal government recognizes such a practice, to the extent that the FDA does not discourage it and Congress expressly forbids the agency from prohibiting it and interfering with or "limiting" the practice of medicine. *See generally The Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001). The state of Indiana also has no prohibition against off-label prescribing by HCPs with prescriptive authority.

SARS-CoV-2 and COVID-19

SARS-CoV-2 is a specific type of virus – a coronavirus – that causes the illness known as COVID-19.²¹ There are currently twelve variants of the SARS-CoV-2 virus present in the United States and several subvariants within those.²² There have been over 63 million reported COVID-19 cases in the U.S., and almost 843,000 deaths connected to COVID-19 infection.²³ In Indiana, there have been over 1.4 million total positive COVID-19 cases and over 19,000 deaths.²⁴

Although the overwhelming majority of COVID-19 cases are "categorized as mild,"²⁵ it can make someone seriously ill and even cause death in some cases. Common symptoms of COVID-19 include fever, cough, achiness, shortness of breath, new loss of taste and/or smell, sore throat, and congestion or runny nose.²⁶ Approved treatments for COVID-19 include remdesivir,

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ Informed consent will be discussed in more detail *infra* under the *Standard of Care for HCPs* section.

²¹ <https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html> (last accessed Jan. 14, 2022).

²² *Id.*

²³ https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days (last accessed Jan. 14, 2022).

²⁴ <https://www.coronavirus.in.gov/2393.htm> (last accessed Jan. 14, 2022).

²⁵ Over 80% of COVID-19 cases are considered "mild." Ahmed *et al.*, *A five-day course of ivermectin for the treatment of COVID-19 may reduce the duration of illness*, *Int'l J. Infectious Dis.* 103 214-216, 214 (2021). Available at [https://www.ijidonline.com/article/S1201-9712\(20\)32506-6/fulltext](https://www.ijidonline.com/article/S1201-9712(20)32506-6/fulltext) (last accessed Oct. 21, 2021).

²⁶ <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html> (last accessed Oct. 28, 2021). This list is not exhaustive, and COVID-19 can present with many different symptoms.

an antiviral medication, for adults and children over the age of 12 years.²⁷ To date, this is the only FDA-approved prescription medication to treat and/or prevent COVID-19. Non-prescription treatment options include taking an over-the-counter fever reducing medication, drinking plenty of water, and rest.²⁸ More serious illnesses may require hospitalization.²⁹

Preventative measures include washing hands frequently, avoiding crowded areas, and social distancing of at least six-feet.³⁰ The Centers for Disease Control (“CDC”) also recommends the wearing of masks for some individuals in certain situations.³¹ Pfizer-BioNTech is currently the only fully FDA-approved vaccine, while the Moderna and Johnson & Johnson vaccines still have Emergency Use Authorization (“EUA”).

Hydroxychloroquine and Ivermectin

This section discusses two medications – hydroxychloroquine and ivermectin – because they were specifically mentioned in more than one of the requests to the OAG, and they are also two of the most widely discussed drugs regarding the treatment and prevention of COVID-19. However, this Opinion should not be construed as advocating or discouraging the prescribing or use of any particular medication or course of treatment for the prevention and/or treatment of COVID-19. The OAG provides legal advice, not medical advice.

Hydroxychloroquine is an anti-parasitic drug that has both anti-viral and anti-inflammatory properties.³² It is an antimalarial that is FDA-approved for the treatment of malaria, lupus, and rheumatoid arthritis.³³ The World Health Organization (“WHO”) lists hydroxychloroquine on its “essential medicines list” as a treatment for both malaria and lupus. Due to its known anti-viral properties, hydroxychloroquine has been studied as a potential treatment and preventative course for COVID-19.³⁴

²⁷ <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-frequently-asked-questions> (last accessed Oct. 28, 2021).

²⁸ <https://www.cdc.gov/coronavirus/2019-ncov/your-health/treatments-for-severe-illness.html> (last accessed Oct. 28, 2021).

²⁹ *Id.*

³⁰ <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html> (last accessed Oct. 28, 2021).

³¹ *Id.* The OAG does not take a stance on vaccination or the wearing of masks in this Opinion, it is simply stating guidelines provided by the CDC.

³² Ip *et. al.*, *Hydroxychloroquine in the treatment of outpatients with mildly symptomatic COVID-19: a multi-center observational study*, BMC Infectious Dis. (2021) 21:72; available at <https://bmcinfctdis.biomedcentral.com/articles/10.1186/s12879-021-05773-w> (last accessed Oct. 21, 2021).

³³ https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/009768s041lbl.pdf (last accessed Nov. 1, 2021)

³⁴ See, e.g., Ip, *supra*, note 32; Mitjà *et. al.*, *A Cluster-Randomized Trial of Hydroxychloroquine for Prevention of Covid-19*, N. Engl. J. Med. 384:5 (2021); available at <https://www.nejm.org/doi/full/10.1056/nejmoa2021801> (last accessed Oct. 22, 2021); Axfors *et. al.*, *Mortality outcomes with hydroxychloroquine and chloroquine in COVID-19 from an international collaborative meta-analysis of randomized trials*, Nature Comm., (2021) 12:2349; available at <https://www.nature.com/articles/s41467-021-22446-z> (last accessed Oct. 22, 2021).

Ivermectin is an anti-parasitic drug that also has anti-viral properties.³⁵ It is FDA-approved for human use in tablet form to treat certain parasitic worms, and in topical form to treat head lice and rosacea.³⁶ The WHO lists ivermectin on its essential medicines list as a treatment for hookworm, scabies, a disease known as “river blindness,” and a number of other parasitic illnesses.³⁷ Ivermectin is also approved to treat animals, including livestock.³⁸ The dosages for human and animal ivermectin are very different; the higher animal dose could be toxic or even deadly to humans who ingest it.³⁹ Like hydroxychloroquine, ivermectin has been studied as a potential medication for the treatment and prevention of COVID-19.⁴⁰

Standard of Care for Health Care Professionals

Legal considerations

Standard of care generally

HCPs must follow established standards of care in providing medical care to a patient; if an HCP breaches that duty and harm to the patient results, the HCP could be liable for medical malpractice.⁴¹ The standard of care can loosely be described as what care similarly-situated HCPs provide in the same general area.⁴² Courts have not required physicians to disclose that a medication is being prescribed off-label or receive informed consent of the patient prior to use unless the issue is material to the case.⁴³ However, determining whether something is “material”

³⁵ Ahmed, *supra* note 25; Chaccour *et. al*, *The effect of early treatment with ivermectin on viral load, symptoms and humoral response in patients with non-severe COVID-19: A pilot, double-blind, placebo controlled, randomized clinical trial*, *Eclin.Med.* 32 (2021) 100720; available at [https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(20\)30464-8/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(20)30464-8/fulltext) (last accessed Oct. 21, 2021).

³⁶ <https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19> (last accessed Oct. 21, 2021). (Hereinafter known as “FDA Ivermectin”)

³⁷ <https://list.essentialmeds.org/medicines/58> (last accessed Oct. 28, 2021).

³⁸ FDA Ivermectin, *supra*, note 36.

³⁹ *Id.*

⁴⁰ *Id.*; see also Chaccour, *supra* note 32; <https://clinicaltrials.gov/ct2/show/NCT04920942> (last accessed Oct. 28, 2021); Mahmud *et. al*, *Ivermectin in combination with doxycycline for treating COVID-19 symptoms: a randomized trial*, *J. Int’l Med. Res.* 49(5) 1-14 (2021); available at <https://journals.sagepub.com/doi/full/10.1177/03000605211013550> (last accessed Oct. 21, 2021); Bryant *et. al*, *Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines*, *Am. J. Therapeutics* 28, e434-e460 (2021); available at https://journals.lww.com/americantherapeutics/Fulltext/2021/08000/Ivermectin_for_Prevention_and_Treatment_of_7.aspx (last accessed Oct. 21, 2021).

⁴¹ 23 *Ind. Law Encyc. Physicians and Surgeons* § 13.

⁴² James B. Riley and P. Aaron Basilius, *Physicians’ liability for off-label prescriptions*, *Hem. & Onc. News & Iss.*, (2007); available at https://www.mcguirewoods.com/news-resources/publications/health_care/off_label.pdf (last accessed Oct. 21, 2021).

⁴³ Wittich *et. al*, *Ten Common Questions (and Their Answers) About Off-label Drug Use*, *Mayo Clin. Proc.* 2012; 87(1):982-990; available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538391/> (last accessed Oct. 21, 2021); Syed *et. al*, *The Law and Practice of Off-Label Prescribing and Physician Promotion*, *J. Am. Acad. Psychiatry Law*

can only be done in hindsight, once the harm has already occurred, so the HCP must decide at the time of prescribing whether to disclose the off-label status to the patient. The mere act of prescribing a medication off-label will not generally be considered malpractice; a patient must also establish that by doing so, he or she was harmed, and the HCP deviated from an accepted standard of practice.⁴⁴

Standard of care in Indiana

In Indiana, as elsewhere, an HCP is also expected to exercise the same skill and administer the appropriate level of medical service as an HCP acting in the same or similar circumstances in the same or similar surroundings.⁴⁵ The patient plaintiff must establish a breach of duty – the standard of care – by the HCP, and that the patient was harmed by such breach.⁴⁶ Relevant to this Opinion, a patient plaintiff would have to establish, by a preponderance of the evidence, that the off-label prescribing was beyond the scope of what any reasonable provider would do in a similar situation, *and* that the patient plaintiff’s injury or harm was a direct result of the use of the off-label prescription medication that no other reasonable HCP would have prescribed for that use.⁴⁷

As noted *supra*, Title 25 of the Indiana Code regulates certain occupations and professions, with Ind. Code ch. 25-1-9 establishing general minimum standards of practice for health professions. While the MLB devotes an entire administrative rule article to standards of professional conduct and the competent practice of medicine, 844 IAC 5-2-5 specifically requires practitioners to “exercise reasonable care and diligence in the treatment of patients based upon generally accepted scientific principles, methods, treatments, and current professional theory and practice.” The MLB’s provisions for the competent practice of PAs are not quite as extensive, as they are found at 844 IAC 2.2-2-6; however, this is to be expected since PAs cannot practice independently, unlike a physician. 844 IAC 2.2-2-6(14) declares prescribing a medication “outside of those drugs included in the prescribing authority delegated by the supervising physician as identified in the supervisory agreement and prohibited under IC 25-27.5-5-4” to be “willful misconduct or the incompetent practice” of a PA. Likewise, 848 IAC 2-2-3 lists behaviors for registered nurses that are considered by the Nursing Board to be unprofessional conduct, or any behavior that fails “to meet the minimal standards of acceptable and prevailing nursing practice, which could jeopardize the health, safety, and welfare of the public”; as noted *supra*, 848 IAC 4 separately establishes the standards of professional conduct for APNs.

Licensing complaint process in Indiana

Ind. Code ch. 25-1-7 establishes the investigation and prosecution process of complaints for regulated occupations and professions. Ind. Code § 25-1-7-2 grants the OAG the authority to “receive, investigate, and prosecute complaints concerning regulated occupations.” Except for

49(1) online (2021); available at <https://pubmed.ncbi.nlm.nih.gov/33234538/> (last accessed Oct. 21, 2021). Also note, informed consent and negligence are two independent issues, though often intertwined in these types of cases.

⁴⁴ Riley and Basilius, *supra* note 42; Wittich, *supra* note 43.

⁴⁵ 23 Ind. Law Encyc. Physicians and Surgeons § 27

⁴⁶ *Id.*

⁴⁷ *Id.*

employees of the OAG in their official capacity, anyone can file a complaint. Ind. Code § 25-1-7-4. The Consumer Protection Division (“CPD”) of the OAG will investigate complaints concerning physicians and will notify the relevant boards concerning certain violations. Ind. Code § 25-1-7-3. After investigating the matter, the CPD Director may recommend disciplinary action against the licensee to the Attorney General; alternatively, the relevant licensing board may also request the same and the Attorney General “shall prosecute the matter before the board, on behalf of the state of Indiana.” Ind. Code § 25-1-7-7.

Ind. Code ch. 25-1-20 – COVID Shield Law

As noted in the *Relevant Laws* section, the COVID Shield Law provides immunity from liability for certain HCPs for certain health care services provided in response to COVID-19. The COVID Shield Law protects an HCP from liability unless the HCP’s actions constitute “gross negligence, willful or wanton misconduct, fraud, or intentional misrepresentation.” Ind. Code § 25-1-20-4(a). This is a much higher bar than the typical negligence standard, but for purposes of this Opinion, it is likely irrelevant anyway, because Ind. Code § 25-1-20-4(b)(3) expressly states that “using” a medicine in a “manner that is not approved” by the FDA would not constitute an action under Ind. Code § 25-1-20-4(a). The OAG reads “using” in this context to encompass both the prescribing by the HCP and actual use by the patient of the medication. Therefore, the COVID Shield Law applies to prescribing hydroxychloroquine, ivermectin, or other medication that is FDA-approved for another use off-label for the treatment and prevention of COVID-19. Unless the law is extended this upcoming legislative session, it will expire April 1, 2022, as well as any liability protections afforded by it, unless the disaster emergency ends prior to that date. Ind. Code § 25-1-20-1.

Off-label use for treatment or prevention of COVID-19 is not *per se* outside the standard of care

The SARS-CoV-2 virus, and thus COVID-19 and the medical field’s knowledge of both, is rapidly evolving. Furthermore, studies on the safety and efficacy of potential treatments and preventative medications conflict in outcomes and results (please refer to Footnote 38 of this Opinion for more detail). The OAG can provide legal expertise but is not in a position to make medical judgments. Those should be left to the HCPs who are trained and skilled in the knowledge to know what is best for their patients. If scientists and public health experts cannot come to a consensus on the safety and efficacy of certain medications, such as ivermectin, then it is reasonable to believe that prescribing them off-label would likely fall within the standard of care.

However, HCPs who prescribe any medication off-label should continue to stay updated on that medication for any changes in the safety or efficacy profile. If an update occurs that would drastically alter the safety or efficacy of a medication, especially in a negative light, this could open the HCP up to liability and potentially land the HCP outside the standard of competent care. As previously noted, to further reduce liability, it is advisable for the HCP to inform the patient of the off-label use and the potential risks of such use. While courts have held that informed consent is not always material, that information cannot be known in any particular case until a harm has already occurred and a lawsuit has been filed.

Off-label prescribing of medications is a generally accepted and widespread practice. Therefore, it is often within the standard of care absent other circumstances that would make such

action medical malpractice or otherwise negligent in some way. The OAG sees no reason, based on the studies available at this time, to distinguish off-label prescribing of medications for the treatment and prevention of COVID-19 from the off-label prescribing of medications for other illnesses and conditions.

CONCLUSION

Off-label prescribing and use of medications are common and widely accepted practices in medicine. Sometimes, such use is the first-line treatment or only treatment method. The practice appears to fall within the standard of care for HCPs in most cases, although there are likely situations where off-label prescribing may fall outside of that standard. Experts disagree and studies conflict on prevention and treatment methods for COVID-19, so it is not unreasonable for HCPs to prescribe medications off-label and it be considered within the standard of care.

The analysis and conclusion in this Opinion are not an official OAG policy statement whether or how to discipline against HCPs and licensing enforcement due to prescribing medications for off-label use. The relevant points in this Opinion – the COVID Shield Law, other Indiana law and administrative rules, standard of care, informed consent, and others – will all be considerations in any complaint case received and investigated, whether it be during the public health emergency or upon the expiration of the COVID Shield Law. Furthermore, the decision to prescribe a medication off-label is one that is best left to consultation between the patient and HCP in consideration of the medical circumstances of each situation. The OAG does not wish to interfere with such issues confined to the patient-doctor relationship. Rather, the OAG’s conclusion provides clear legal guidance to HCPs as well as Hoosiers under their care.

Sincerely,



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Attorney General of Indiana

John Walls, Chief Counsel, Advisory
William H. Anthony, Asst. Chief Counsel, Advisory
Philip Gordon, Section Chief, Advisory
Hilari A. Sautbine, Senior Deputy Attorney General